1	2	3	4
10	Jammu & Kashmir		2.3
11	Orissa	2.8	2.4
12	Gujarat	2.9	2.6
13	Haryana	3.2	2.6
14	Assam	3.1	2.7
15	Chhattisgarh		3.1
16	Jharkhand		3.2
17	Madhya Pradesh	4.0	3.4
18	Rajasthan	4.1	3.4
19	Bihar	4.5	3.9
20	Uttar Pradesh	4.7	3.9

SOURCE: Sample Registration System, O/o Registrar General of India, Ministry of Home Affairs

Undue delay in getting various permission and pending applications

*97. DR. V. MAITREYAN: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether even after streamlining the system of operations and inducting more personnel, DCGI office is not able to approve applications by the prescribed deadline;

(b) if so, the reasons therefor;

(c) whether the present DCGI goes on frequent tours and has not delegated the powers of approval to his subordinate officials causing undue delay;

(d) if so, the immediate action proposed to put the system on fast track;

(e) the number of applications as on January 31, 2009 pending in each category of approvals and how many have been cleared; and

(f) whether there is also selective amnesia in the department to clear only a few applications?

THE MINISTER OF HEALTH AND FAMILY WELFARE (DR. ANBUMANI RAMDOSS): (a) and (b) Strengthening, streamlining and capacity building of the regulatory body *i.e.* CDSCO is underway. While certain vacant posts have been filled up, others are in different stages of recruitment with the UPSC. About 72 new posts of Drug Inspectors and Technical Officers have been recently created and the UPSC has already advertised the post of Drug Inspectors. Various categories of applications are processed in the office of DCG(I) as per the Drugs and Cosmetics Rules keeping in view the prescribed timelines. It may be mentioned that although the timeline prescribed in Drugs and Cosmetics Rules for grant of import registration of drugs is 9 months, the office of DCG(I) is granting the same in 3 months. NOC for export is generally granted in around 2 weeks.

Requirements and guidelines for various approvals are specified in Drugs and Cosmetics Act and Rules made there under. For grant of such approval, applicants are required to submit documents as per the Rules. In case of any deficiency, applicants are asked to submit clarification/information which may delay the grant of approval.

(c) and (d) DCG(I) is the head of CDSCO, which also has Zonal offices, Sub-Zonal offices, Port Offices, and Drug Testing Laboratories. Apart from this, DCG(I) also has to interact with State Drugs Controllers. DCG(I) is also in several Committees. Therefore, to meet official obligations, DCG(I) has to undertake tours. Delegation of authority to sign approval/license during such short term tours may not be feasible as such delegation of authority to sign various approvals/licences is required to be made with approval from the Central Government.

However, for grant of NOCs for export of banned drugs and New Drugs, DCG(I) has already delegated the authority to his immediate subordinate officer. Further delegation of power would be considered once the recruitment of senior functionaries is completed.

(e) Number of various categories of applications as of January 31, 2009, which are at various stages of processing are given in the Statement (*See* below).

(f) No, Sir. All applications are processed as per the Drugs and Cosmetics Rules keeping in view the prescribed timelines.

Statement

Status of various categories of applications from January 2008 to 31st January, 2009 (Approx)

Sl.No.	Subject	No. of Applications Received from January 2008 to 31st January 2009 (Approx.)	No. of remaining applications under process as on 31st January, 2009
1.	New Drug Applications	2000	300
2.	Global Clinical Trials	300	42
3.	Vaccines and Biotech	50	10
4.	Medical Device	500	30
5.	Diagnostic Kit	1000	3
6.	Export NOCs	3000	100
7.	Test Licence	7500	219
8.	Blood Bank Licence	275	4
9.	Import Registration	500	75
10.	Import Licence	2000	45